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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,939	05/30/2001	Douglas A. Amorese	10010791-1	8714

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AGILENT TECHNOLOGIES, INC.
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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No.	Applicant(s)	
	09/870,939	AMORESE ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-20 and 38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-20 and 38-41* is/are rejected.

7)☒ Claim(s) *41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 December 2003 has been entered.

Status of the Claims

2. This action is in response to papers filed 19 December 2003 in which claims 1, 5-7, 11-15, 39-41 were amended. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 25 August 2003 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-3, 5-20, 38-41 are under prosecution.

Claim Objections

3. Claim 41 is objected to because of the following informalities: in step (a), "comprises" is misspelled

Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3, 5-10, 14, 38 and 41 are rejected under 35 U.S.C. 102(3e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bao et al (U.S. Patent No. 6,251,601, filed 2 February 1999).

Regarding Claim 1, Bao et al disclose an array comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides and a second set of features having single-stranded polynucleotides of about 100 nucleotides. Specifically, Bao et al teach an array comprising cDNA and oligomers (Column 6, lines 32-34) wherein the cDNA target elements are more than 400 bp (Column 8, lines 45-54) and the oligomers are less than 100bp, (Column 8, lines 27-31).

Bao et al further teach the array wherein the target elements comprise full length and partial length cDNAs from about 100bp to 5,000bp (Column 8, lines 45-48) and wherein the partial cDNAs are synthesized as oligos of 8-100bp (Column 8, lines 27-42).

The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Bao et al is silent with regard to the claimed range of "at least 400bp" and "no more than 100bp". However, the lengths recited in the Claims are deemed to be inherent in the ranges taught by Bao et al because they specifically teach overlapping ranges.

The courts have stated where the claimed ranges "overlap or lie inside the ranges disclose by the prior art" and even when the claimed ranges and prior art ranges do not overlap but are closed enough that one skilled in the art would have expected them to have similar properties, a *prima facie* case of obviousness exists (see *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775. 227 USPQ 773 (Fed. Cir. 1985) (see MPEP, 2144.05 I.).

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the sequence length of Bao et al because they specifically teach that one of ordinary skill in the art would adjust the sequence length to provide the sequence information required (Column 8, lines 23-27). Furthermore, Bao et al teach that a target sequence will be broken in to fragments of different lengths and complexity (Column 8, lines 16-21). And one of skill would adjust fragment lengths to optimize hybridization and signal (Column 8, lines 23-27). Hence, one of ordinary skill in the art would have been motivated to provide an array of cDNA fragments of differing lengths (i.e. more than 400bp and less than 100bp) as suggested by Bao et al for the expected benefit of analyzing gene expression under optimized conditions as taught by Bao et al (Column 8, lines 16-26).

The burden is on applicant to show that the claimed ranges are either different or non-obvious over that of Bao et al.

Regarding Claims 2 and 3, Bao et al teach an array comprising cDNA and oligomers (Column 6, lines 32-34) wherein the cDNA target elements are more than 400 bp (Column 8, lines 45-54) and the oligomers are less than 100bp, (Column 8, lines 27-31) but they do not teach a ratio of short to long polynucleotides. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made, based on experimental design wherein expressed sequences are of interest, to provide an array comprising the claimed ratios. For example, an experiment designed to analyze expressed sequences of at least 400 nucleotides, an array comprising mostly sequences of at least 400 nucleotides would provide optimal analysis of the 400 nucleotide + sequences. Therefore, one skilled in the art would have been motivated to design the array having a short (less than 100) to long (at least 400) polynucleotide ratio of at least 1:10 or 1:20 to thereby optimize experimental condition and maximize experimental results.

Regarding Claim 5, Bao et al disclose the array wherein the first polynucleotides are from enzymatic processing (i.e. cloning) and the second polynucleotides are synthetic (i.e. obtained from commercial sources) (Column 8, lines 445-65). While Bao et al teaches the claimed process for making the first and second polynucleotides, it is noted that the claimed process for making the polynucleotides does not limit the polynucleotides.

Regarding Claim 6, Bao et al disclose the array wherein the first polynucleotides have a length of at least 500 nucleotides (Column 8, lines 55-58).

Regarding Claim 7, Bao et al disclose the array wherein the first polynucleotide cDNAs have a length of at least 1000 nucleotides (Column 8, lines 45-48) and the oligomeric target elements preferably range in size from 20-80 nucleotides (Column 8, lines 27-28). Furthermore, they teach that one of ordinary skill would adjust the lengths to optimize hybridization for any given hybridization (Column 8, lines 16-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cDNA and oligomer target elements of Bao et al and to provide the microarray with target

elements of more than 1000 and no more than 80 nucleotides as suggested by Bao et al (Column 8, lines 45-48) to thereby optimize the hybridization based on the desired procedure as taught by Bao et al (Column 8, lines 16-26).

Regarding Claim 8, Bao et al disclose the lengths exclude stilt portions i.e. Bao et al teach the polynucleotides are attached to the support (Column 11, lines 50-54) and do not teach the polynucleotides comprise stilts. Therefore, the polynucleotide length excludes a stilt portion.

Regarding Claim 9, Bao et al disclose the array wherein the features are arranged in a rectangle (Fig. 1A).

Regarding Claim 10, Bao et al disclose the features are arranged in lines (Fig. 1A) with at least some of the lines including features of both first and second sets i.e. the target elements are interspersed (Column 10, lines 31-38).

Regarding Claim 14, Bao et al disclose the array wherein the sequence of the second polynucleotide is contained within the first polynucleotide i.e. target elements are broken into fragments of differing length (Column 8, lines 16-26).

Regarding Claim 38, Bao et al disclose the microarray wherein features have the same polynucleotide i.e. array manufacture via deposition of a different nucleic acid at each spot (Column 9, line 66-Column 10, line 10).

Regarding Claim 41, disclose an array comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides and a second set of features having single-stranded polynucleotides of about 100 nucleotides. Specifically, Bao et al teach an array comprising cDNA and oligomers (Column 6, lines 32-34) wherein the cDNA target elements are more than 400 bp (Column 8, lines 45-54) and the oligomers are less than 100bp, (Column 8, lines 27-31) and wherein each feature contains only one sequence i.e. array manufacture via deposition of a different nucleic acid at each spot (Column 9, line 66-Column 10, line 10).

7. Claims 11-13, 15-20 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al (U.S. Patent No. 6,251,601, filed 2 February 1999) in view of CLONTECHniques (July 2000).

Regarding Claims 11-13 and 39-40, Bao et al disclose a microarray comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides (i.e. genomic DNA target elements, Column 8, lines 55-58) and a second set of features having single-stranded polynucleotides of about 100 nucleotides (i.e. cDNA target elements, Column 8, lines 45-48) wherein the microarray comprises both genomic DNA and cDNA target elements (Column 10, lines 31-35 and Claim 5) but they do not teach the array comprising a second set of features wherein the sequences of the second set of features is not within the first polynucleotide sequence. However, Clontech teaches a similar microarray comprising a second set of polynucleotides wherein the second set comprises control sequences not found in the first set of polynucleotides (right column and Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the control probes of Clontech to the kit of Bao et al for the expected benefit of providing means for troubleshooting hybridizations as taught by Clontech (last paragraph).

Regarding Claim 15, Bao et al disclose an array comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides and a second set of features having single-stranded polynucleotides of about 100 nucleotides. Furthermore, they teach the microarray and reagents for using the array combined into a kit format (Column 14, line 63-Column 15, line13) but they do not specifically teach the reagents comprise polynucleotide controls at least 70% complementary to the second polynucleotides. However, microarray kits comprising control probes complementary to control polynucleotides on the microarray were well known in the art at the time the claimed invention was made as taught by Clontech. It would have been obvious to one of ordinary skill in the art at the time the claimed invention

was made to apply the control probes of Clontech to the kit of Bao et al for the expected benefit of providing means for troubleshooting hybridizations as taught by Clontech (last paragraph).

Regarding Claim 16, Clontech teaches that the control probes are complementary to control polynucleotides on the microarray (last paragraph).

Regarding Claim 17, Clontech teaches that the control probes are labeled (last paragraph).

Regarding Claim 18, Clontech teach that the ratio of first set of features (i.e. target-specific) to the second set of features is at least 10/1 (i.e. the microarray comprises two control spots, Fig. 1 and last paragraph).

Regarding Claim 19, Clontech teach that the ratio of first set of features (i.e. target-specific) to the second set of features is at least 20/1 (i.e. the microarray comprises two control spots, Fig. 1 and last paragraph).

Regarding Claim 20, Clontech teaches the kit comprises instructions (right column).

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741 until 13 January 2004. The examiner can normally be reached on 6:00 TO 3:30 Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0507.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
March 1, 2004